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10/723,439

11/26/2003

Harry S. Winchell

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EXAMINER
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HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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11/02/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

### Application No.

10/723,439

### Applicant(s)

WINCHELL, HARRY S.

### Examiner

Raymond J. Henley III

### Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2,5,25,26 and 33-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,5,25 and 26 is/are rejected.
- 7) ☒ Claim(s) 33-40 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**CLAIMS 2, 5, 25, 26 AND 33-40 ARE PRESENTED FOR EXAMINATION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application on October 12, 2007 after final rejection set forth in the previous Office action dated August 23, 2007. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on October 12, 2007 has been entered. Accordingly, claims 2 and 25 have been amended and claims 3, 4, 6-12, 14, 18, 21-24 and 41-50 have been canceled.

***Claim Construction/Interpretation***

Applicant's remarks incorporate a definition for a complex compound which distinguishes such from a compound in its salt form. In particular, the bond existing between a metal and the ligand in a complex compound is intermediate to a covalent and electrostatic, (a.k.a., ionic), bond. The present claims require the presence of a complex compound and such compound is now appropriately viewed as meaning those types of compounds provided in the definition for a complex compound.

***Remaining Issues/Claim status***

To the extent that the Winchell et al., (U.S. Patent No. 5,874,573) was relied on by the Examiner for its teachings of salt compounds, the Examiner now withdraws this reliance. The claims of Winchell et al. fail to teach or suggest complex compounds of any type, only salts. As such, the double patenting rejection maintained in the previous Office dated October 12, 2007 has been overcome by Applicant's response and such is here withdrawn.

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Insofar as the specification of Winchell et al., however, teaches complex compounds, (e.g., col. 68), with metals of the type presently claimed, as well as other reasons explained below, Examiner continues to rely on this reference for rejecting claims 2, 5, 25 and 26 under 35 U.S.C. § 103(a).

Applicant's remarks, (page 8), further incorporate reference teachings which establish the unpredictability of employing antioxidant substances, because they are, in fact, antioxidants, for providing cardioprotective or neuroprotective activity. In view thereof, the Examiner's position that from the teachings in Winchell et al. that the compounds are antioxidants, the methods of therapy of present claims 33-40 would have been obvious, (in view of the teachings provided by Weglicki, (U.S. Patent No. 5,854,287)), is no longer tenable.

Accordingly, claims 33-40 are no longer rejected under 35 U.S.C. § 103(a) and Weglicki is no longer relied on. Claims 33-40 are now objected to as depending from a rejected base claim, but are otherwise in condition for allowance.

***Claim Rejection - 35 USC § 103***

Claims 2, 5, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winchell et al., (U.S. Patent No. 5,874,573), already of record, for the reasons of record as set forth in the previous Office action throughout pages 2-4 as applied to claims 2-12, 14, 18, 21-26, which reasons are here incorporated by reference.

Applicant's remarks at pages 7-9 of the amendment have been given careful consideration, but fail to persuade the Examiner of non-obviousness.

The present claims are directed to pharmaceutical compositions comprising complex compounds of formula (I) having either calcium or magnesium as the metal. As presented in the

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previous Office action, such complex compounds, (i.e., not salts), are suggested by Winchell et al. in teaching specific calcium- and magnesium-ligand complex compounds (e.g., col. 68, lines 6-16), and by providing a focused teaching in claims 13 and 14, (col. 74), of the presently claimed phosphoryl ligand.

Applicant has traversed this conclusion of obviousness and has provided objective evidence of unexpected results. In particular, in Example 7 of the present specification it has been shown that, as compared to a trissodium complex, a monomagnesium- monosodium-complex, (herein after "complex I"), as well as a monocalcium- monosodium-complex, (hereinafter "complex II") were unexpectedly superior in conditions of ischemia following reperfusion of heart tissue. Also, it was demonstrated that complex II provided results involving more functional parameters than complex I.

The above results do not overcome the present presumption of obviousness, however, because the claims are not commensurate in scope with the evidence offered to show unexpected results, (see MPEP § 2144.08(II)(B)).

In particular, the present claims require only that the metal is selected from magnesium and calcium and thus none are limited to complex compounds having the monosodium moiety as in complex I and complex II. Simple calcium- or magnesium-complex compounds were simply not tested and it would not be proper to speculate as to the results that could or could not be achieved by non-tested compounds.

Further, *even if* the claims were limited to complex compounds having the monosodium/monocalcium or monosodium/monomagnesium moieties of the test compounds, the claims would not be commensurate in scope with the test results because claims 2, 5, 25 and

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26 are composition-type claims and not method-type claims. The results of Example 7 necessarily depend on the composition being administered whereas the present claims define a static entity which is in no way limited by such a method step, i.e., step of administration. An example of a characteristic of a composition which the Examiner would deem probative for showing non-obviousness would be a physical characteristic of the composition, such as shelf-life or stability.


Accordingly, for the above reasons, the claims are deemed properly rejected.

None of the claims are currently in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Raymond J Henley III  
Primary Examiner  
Art Unit 1614

October 30, 2007